

26 WEST 61ST STREET
NEW YORK NY 10023

ART UNIT	PAPER NUMBER
----------	--------------

1631

DATE MAILED:

10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/643,407

Applicant(s)

PEER ET AL.

Examiner

Channing S Mahatan

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

Art Unit: 1631

DETAILED ACTION

Election/Restrictions

Applicant is required to elect one (1) specie from each of the three (3) specie election requirements.

FIRST SPECIE ELECTION REQUIREMENT

1. This application contains claims directed to the following patentably distinct species of the claimed invention: First through Sixth embodiments in the specification on pages 9-22.

- I. First Embodiment: specifically claim 12
- II. Second Embodiment: specifically claim 14 (Algorithm B)
- III. Third Embodiment: specifically claim 16 (Algorithm C)
- IV. Fourth Embodiment: specifically claim 17 (Algorithm D)
- V. Fifth Embodiment: specifically claim 18-21
- VI. Sixth Embodiment: specifically claim 23

I. (pg.9-15) Requires that the unknown target sequence and reference sequence differ from each other by nucleotide substitutions without insertions or deletions. II. (pg.15-17) Requires that the unknown target sequence and the reference sequence differ by substitutions and deletions only, without insertions; noted to be in reference to Algorithm B pg. 16 line 5. III. (pg.17-18) Requires that there is no difference in substitutions, insertions, and deletions; noted to be in reference to Algorithm C pg. 18 line 15. IV. (pg.18-20) Requires the use of Hidden Markov Model to determine homology between nucleotide sequences. V. (pg. 20-21) Requires the use of graph nodes (HMM & k-mers). VI. (pg.21-22) Requires the use of 2 phase filtering.

Art Unit: 1631

Under these specifications stated within the application the above species are considered distinct, establishing a separate status in the art when they are classified together and a different field of search. Therefore, a species election is required.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-11, 13, 15, 22, and 24-32 are generic.

SECOND SPECIE ELECTION REQUIREMENT:

2. This application contains claims directed to the following patentably distinct species of the claimed invention: Claim 28.

- I. Detecting or genotyping Single Nucleotide Polymorphisms.
- II. Detecting or genotyping of genetic syndromes or disorders.
- III. Detecting or genotyping somatic mutations.
- IV. Sequencing a polynucleotide whose function is related to the function of the reference polynucleotide.

I. Detection or genotyping of Single Nucleotide Polymorphisms requires a single nucleotide variation in a genetic sequence that occurs at a frequency of at least 1% in the population. II. Detection or genotyping of genetic syndromes or disorders consists of a single or multiple nucleotide variations within a germ line or somatic line. III. Detecting or genotyping somatic mutations consist of a single or multiple nucleotide variation within a somatic line only. IV. Sequencing a polynucleotide whose function is related to the function of the reference polynucleotide restricts sequencing to function only. Under these interpretations the above

Art Unit: 1631

species is considered distinct, establishing a separate status in the art when they are classified together and a different field of search. Therefore, requiring a species election.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-32 are generic.

THIRD SPECIE ELECTION REQUIREMENT:

3. This application contains claims directed to the following patentably distinct species of the claimed invention: Claim 30.

I. Polynucleotides sequenced.

II. Polypeptides sequenced.

I. Polynucleotide sequence is a polymeric sequence consisting of a number of nucleotides (adenine, guanine, cytosine, thymine, and uracil). II. Polypeptide sequence is a sequence containing many molecules of amino acids (any of the 20 amino acids that have the basic formula $\text{NH}_2\text{CHR}\text{COOH}$). Under these definitions and pertaining to the computational algorithms the two sequences are considered distinct, establishing a separate status in the art when they are classified together and a different field of search. Therefore, a species election is required.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1-29, 31-32 is generic.

Art Unit: 1631

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1631

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Pauline Farrier, whose telephone number is (703) 305-3550 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *October 18, 2001*

Examiner Initials: *CSM*

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER